Sulfolane Toxicity Meeting

Friday, February 4th, 10 am – 11:15 am Alaska time

Attendees

Selene Chou, ATSDR Division of Toxicology and Environmental Medicine, Chair ATSDR MRL Workgroup

Jim Durant, ATSDR Emergency Response Coordinator with DTEM

Marcia Bailey, EPA Region 10

Chris Cubbison, EPA, National Center for Environmental Assessment, Associate Director for Superfund Technical Support Center (STSC)

Mike Troyer, EPA Acting Division Director for STSC

Nim Ha, AK Dept. of Health and Social Services, Environmental Public Health Program (EPHP) Manager

Cassie Kirk, DHSS, EPHP Health Assessor

Ann Farris, AK Dept. of Environmental Conservation (ADEC), Contaminated Sites Project Manager

Marty Brewer, ADEC Risk Assessor

Stephanie Pingree Buss, SPB Consulting – consultant for ADEC

Meeting Summary

1) Introductions
    a) Background
        i) Approx. 200 homes with detectable levels of sulfolane in wells
        ii) Municipal wells have low-level detection (7 – 10 ppb)
        iii) No regulatory level for sulfolane
2) Status of PPRTV review – U.S. EPA
    a) Dr. Cubbison –
        i) Formally place sulfolane in queue for PPRTV review; evaluation underway
        ii) Initial draft due 2/14
        iii) Review process
            (1) Internal EPA panel of first level peer review
            (2) Panel of 3 subject matter experts (6 weeks for review)
            (3) Final EPA review and management review
        iv) Can release numbers to DEC/DHSS at external peer review stage
        v) Preliminary conclusions
            (1) Will be able to develop PPRTV inhalation values based on Anderson 1977
            (2) Will develop an oral screening value based on HLS, but because unpublished study cannot develop PPRTV; oral screening value will be placed in the appendix (aka

"appendix value"), and as such, will not have as much weight as a value within the body of the report.

(3) EPA will not use unpublished studies for establishing PPRTVs

(4) Screening values can be used for ranking (4th level in hierarchy)

vi) Contractors looked at Zhu study

(1) Could not get details of study (i.e. method and dosing schedule)

vii) Timing – couple months or more, Spring 2011 external review

(1) Final Summer 2011 (optimistic schedule)

3) Status of ATSDR review and health consult

a) Jim Durant -

i) Use of studies

(1) Did not use HLS because ATSDR general preference is to use open and transparent data

(2) Found Zhu study as more sensitive endpoint than HLS

(3) Need published study to develop MRL

ii) Status of review

(1) Drafted another health consultation (initial one published February 3, 2010)

(a) Gone through internal ATSDR review and review from members of MRL group from ATSDR's DTEM

(b) December sent for external peer review by EPA Region 10, Region 8, NCEA, FDA and NIOSH

(i) Received comments from everyone but EPA Region 10

(ii) Comments were substantial

(c) Next step is to integrate comments, clearance review and release

(2) Timing for release - couple of months best case scenario

4) Other Issues

a) IRIS queue is unknown but EPA will check (*follow-up from Dr. Cubbison is that sulfolane is <u>not</u> on the IRIS track)*

b) DEC's concern that two documents will be released to public and will disagree with each other

i) DEC can possibly work with RP/manufacturers to get additional data or research

5) Identification of potential data gaps or research needs

a) Getting HLS published

i) ATSDR and EPA have in the past had critical studies externally peer-reviewed

(1) DEC could encourage that for the HLS

(a) IRIS program has contract for peer review

(i) EPA will look into method for review for HLS

(b) DEC to talk with PRP to get document released for peer review

b) Pursue finding authors of Zhu paper to get information on route of exposure and schedule of dosing

i) 50% of subchronic data is unavailable without getting additional info from Zhu study

ii) ATSDR has relationship with CDC China

iii) Jim Durant to look for contacts but everyone else should look at their contacts, as well

c) QSAR – carcinogenicity

i) Would any additional information be useful to PPRTV?
   (1) EPA not doing much with computational modeling (i.e. QSAR)
   (2) EPA has done it in cases where the structure is similar enough to other compounds as a surrogate chemical that is already on IRIS or PPRTV
      (a) Not suggested for sulfolane in EPA review

d) Chronic toxicity needs
   i) The fastest way to reduce uncertainty in oral value is a developmental toxicity study. If lab is set up to do this type of study, could be done in a manner of weeks or months. Publishing takes longer but study could do study quickly.
      (1) OECD did some work on birth index
         (a) Would need to be published study
         (b) With summary in OECD could possibly use for screening values
   ii) Carcinogenicity
      (1) EPA found no studies on carcinogenicity; weight of evidence discussion would indicate no evidence of sulfolane
      (2) ATSDR hasn't identified any studies that looked at carcinogenicity
         (a) Did use QSAR to determine if expect to be carcinogenic – response was a strong "no"
   iii) Liver toxicity appears most sensitive endpoint
      (1) Endpoints - immunological system and hepatic system
      (2) ATSDR agrees guinea pig and immunological (shrinkage of white pulp in speen) endpoints
         (a) Chronic toxicity study to look at guinea pig and immunological study would be helpful

6) Adequacy of toxicity data for sulfolane
   a) PPRTV – If the values are in the main text there is a discussion of confidence in value and confidence of database; if in document there is sufficient data to use study
   b) Current EPA evaluation will acknowledge limitations of current data, in respect to carcinogenicity as well
   c) Quite a few IRIS RfDs have used sub-chronic studies
      i) ATSDR feels there is sufficient data for provisional values
7) Continued coordination/Next Steps
   a) Get HLS released and reviewed
   b) Find Zhu author
   c) DEC can facilitate another call in a month – March